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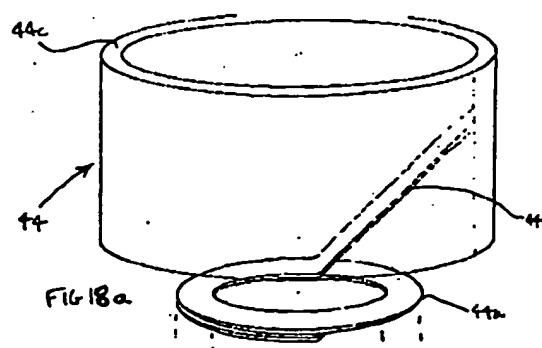
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(54) Gel injection adjustable keratoplasty.

(57) A spatula for use in delaminarizing a portion of the cornea when altering the radius or curvature of the central cornea region, said spatula comprising a flat wire (44a) formed into a helicoidal shape and a handle means (44c) for manipulation of the said flat helicoidal wire to delaminarize said portion of the cornea. Preferably said handle means (44c) has a structure giving the surgeon an unobstructed view of the corneal surface, for example by comprising an annular member. Also provided is a surgical kit for use in altering the radius of curvature of the central corneal region of the eye.



EP 0 557 128 A1

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The present invention relates to a technique for intra-operative correction of refractive error to eliminate the need for eyeglasses and contact lenses. More particularly, the invention relates to a technique for surgically correcting myopia and astigmatism by controlled interlamellar annular injection of a polymeric gel at the corneal periphery so as to modify the corneal curvature, while sparing the central optical zone.

The ideal surgical procedure in refractive surgery could be defined as one which allows all the advantages of eyeglasses or contact lenses, that is, one which offers effectiveness or a wide range of corrections, allowing correction of ametropias both large and small; accuracy or predictability, allowing for correction of a certain amount of ametropia with precision; alterability or reversibility, so that if ocular refractive changes occur it might be possible to adjust the correction again; innocuousness or without complications, that is the procedure does not lead to adverse situations; visual quality without alterations in the size of the image or of the visual field; technical simplicity, that is not requiring sophisticated techniques to be put into practice; availability; low cost; and aesthetically acceptable on the part of the patient.

A number of surgical techniques have been proposed which have the object of intra-operative correction of refractive error. Examples are Radial Keratotomy, Keratomileusis, Epikeratoplasty, and Excimer Laser Reprofiling of the Corneal Surface also known as Photo Refractive Keratoplasty (PRK). These methods work with the characteristics of the cornea in order to modify either its curvature or its refractive index. Perhaps the more widespread method and the one which best approaches the objects noted above is radial keratotomy, basically because it can be performed at low cost without the need for additional materials. However this procedure has a number of limitations, including the presence of adverse situations (glare) and a lack of stability, predictability (hypercorrection or hypocorrection) and reversibility. The remaining procedures described and presently in use demand very sophisticated surgical equipment requiring very specialized training and also the use of synthetic or natural materials that reduce the likelihood of the procedure being available in the average clinic. Further, with the present surgical techniques it is not possible to accurately predict the patient's refractive outcome, due in part to corneal hydration and subsequent wound healing processes.

Yet a further prior procedure made use of a rubber annular implant (intrastromal rings) which were surgically inserted to alter corneal curvature. However, that procedure, which was introduced in 1986 by the inventor of the subject procedure, involved stromal delamination of the central optical zone and, in addition, precluded intra-operative adjustment of the patient's refractive power.

Therefore, there remains a need for a surgical

technique which can achieve intra-operative correction of refractive error to eliminate the need for eyeglasses and contact lenses by modifying the corneal curvature which avoids delamination of the central optical zone and permits intra-operative adjustment of the patient's refractive power, and which is also reversible. There further remains a need for such a technique wherein the surgical equipment is relatively inexpensive and only moderate skills are required.

The present invention relates to a technique and set of surgical instruments which allow for the surgical correction of myopia and astigmatism by controlled injection of a polymeric gel or elastomer at the corneal periphery without interfering with the central cornea and endothelium. More particularly, the surgical technique of the invention allows for subtle modification of the corneal curvature by interlamellar injection of a synthetic or natural polymeric gel at the corneal periphery while sparing the optical zone. In accordance with the inventive surgical procedure, a partial depth, radial incision is made outside the optical zone. A corkscrew-like delaminator, in the form of a helicoidal spatula, is inserted through the incision to form an annular track centered about the corneal apex. A modified needle is then fully inserted in the interlamellar track formed by the delaminator and a transparent gel is manually injected while retracting the needle, thus filling the annular channel, or the gel can be directly injected into the channel. By monitoring the corneal shape with an automatic keratometer, for example, emmetropia can be achieved intra-operatively by controlling the amount of gel injected and by corneal massage. Using a surgical keratometer mounted to an operational microscope, the final corneal power is adjusted by removal of a portion of the gel.

Thus, the use of an injectable substance gives the method, in addition to technical simplicity, the possibility of adjusting the quantity of material to obtain the desired correction. It is also possible to extract this material to reverse the procedure, or augment its volume if necessary.

Other objects, features, and characteristics of the present invention, as well as the methods of operation and functions of the related elements of the structure, and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures.

In the drawings:

FIGURE 1 is a schematic perspective view showing the use of a caliper to locate and mark the central cornea and incision site in accordance with the invention;

FIGURE 2 is a schematic perspective view of an ultrasonic pachymeter for measuring corneal

thickness in accordance with the procedure of the invention;

FIGURE 3 is a perspective view of a diamond knife equipped with a micrometer;

FIGURE 4 is a schematic cross-sectional view of an incision formed in accordance with the invention;

FIGURE 5 is a schematic elevational view showing the incision of the cornea in accordance with the invention;

FIGURE 6 is a schematic elevational view showing the insertion of a blunt spatula in accordance with the invention for separating the lamella;

FIGURE 7 is a schematic elevational view of the insertion of a shoehorn-like device for facilitating insertion of a corkscrew delaminator in accordance with the invention;

FIGURE 8 is a schematic elevational view of the insertion of a corkscrew delaminator;

FIGURE 9 is a perspective view, partly in cross section and partly broken away for clarity, illustrating the formation of an annular track with the corkscrew delaminator in accordance with the invention;

FIGURE 10 is a schematic elevational view of the incision site following complete insertion of the corkscrew delaminator;

FIGURE 11 is a schematic cross-sectional view showing the injection of gel with the needle in accordance with the invention;

FIGURE 12 is a perspective view, partly in cross-section and partly broken away for clarity, showing the retraction of the needle while the gel is injected;

FIGURE 13a is a schematic cross-sectional view of the cornea with the needle within the annular track;

FIGURE 13b illustrates the track with gel so as to bulge the corneal posterior lamellae and flatten the central corneal optical zone;

FIGURE 14 is a schematic perspective view illustrating localised corneal shear variations generated at the limbus which produces astigmatism and their effect on the gel injected in accordance with the invention;

FIGURE 15 is a schematic top plan view of a modified procedure in accordance with the invention;

FIGURE 16 is a schematic cross-sectional view of gel injector suitable for use in accordance with the invention;

FIGURE 17 is a plan view of a track width equalizer for use in accordance with the invention;

FIGURE 18a is a perspective view, partly in phantom, of a different embodiment of the corkscrew delaminator in accordance with the invention;

FIGURE 18b is a cross-sectional view of the helicoidal section of the corkscrew delaminator of

FIGURE 18a;

FIGURE 18c is a fragmentary enlarged view of one embodiment of the tip of the corkscrew delaminator of FIGURE 18a;

FIGURE 18d is a fragmentary enlarged view of another embodiment of the tip of the corkscrew delaminator of FIGURE 18a;

FIGURE 18e is a fragmentary enlarged view of still another embodiment of the tip of the corkscrew delaminator of FIGURE 18a;

FIGURE 19 is a schematic cross-sectional view of the annular track formed in the cornea with the delaminator shown in FIGURES 18a and 18c; and

FIGURE 20 is a schematic cross-sectional view of the annular track formed in the cornea with the delaminator shown in FIGURES 18a, 18d and 18e.

The exact physical properties of the cornea and scleral limbal tissues have not been determined. However, if the cornea resists stretching, it can easily be delaminated. The large differential in modulus of elasticity between the two orthogonal corneal planes is responsible for the effects observed with the procedure of the invention.

The collagen lamellae are laid parallel to Bowman and Descemet layers and have an elastic modulus of approximately 10^8 Nm^2 . These lamellae are weakly bounded and can be easily separated.

The scleral-limbal region forms an annulus (the corneal limbus) much more rigid than the cornea and act as a reference frame with respect to corneal deformation. With the procedure of the invention, the limbus geometry and physical characteristics remain stable (unchanged). Therefore, the procedure of the invention causes a redistribution of the nominal corneal stresses produced by the positive intraocular pressure. This redistribution causes a change in the corneal shape with a flattening of the central corneal radius of curvature and a steepening of the site of gel injection. However, the inner and outer corneal surface areas are kept constant. Therefore, little change occurs in stress applied along the individual lamella. As the laminar network is kept intact except for the small incision site, a very minimal wound healing effect is expected. Thus, the keratometric changes produced by the procedure of the invention are expected to be stable in long-term follow up.

The procedure in accordance with the invention is as follows:

First, the central cornea and the incision site are defined and marked on the eyeball 10 with the help of a standard caliper 12 as shown in FIG. 1. Specifically, the surface of the eyeball is dried with blotting paper and marked with a compass, for example a Castroviejo Caliper #E 2404 available from Storz, Inc. having blunt needles or points which have been previously soaked with ink from an epidermic labeler.

such as #150 available from Devon, Inc. The ink soaked needles are placed on the eyeball to mark the corneal center and the incision site between about 2.5 and 3.5 mm from the apex, a distance corresponding substantially to the internal radius of the corkscrew delaminator used to form the intra-laminar canal in accordance with the invention. Additional marks may be made at that predetermined distance from the corneal center to mark a guide for the dissector to follow during the surgical manoeuvre. Once the central cornea and incision site have been selected and marked, the corneal thickness is determined with a conventional ultrasonic probe and pachymeter 14 at the corneal center and at the incision site as shown schematically in FIG. 2.

A partial depth incision 20 is then performed at the incision site with a diamond knife 16 which is equipped with a micrometer (not shown) having a footplate 18 (FIG. 3). The blade length is adjusted to about 86% of the corneal thickness, as measured by the pachymeter. The knife is then used to form a radial incision to a depth D of between 75% and about 85% and most preferably between about 75% and about 80% of the corneal thickness T. To obtain a flat bottomed incision with vertical walls, the diamond blade can be reversed and moved radially with respect to the center of the cornea (FIG. 4). The foregoing two step procedure with the diamond blade can be avoided by the use of a flat-edged blade. The insertion of the diamond knife 16 to the predetermined $80\% \pm 5\%$ depth of the cornea 22 is illustrated in particular in FIG. 5. The incision is performed to a length L of about 1.0 mm or less and most preferably about 0.4 mm which is slightly less than the width of the spatula to be used, described more fully below, so that the latter fits perfectly into the incision. The incision is preferably made as small as possible so as to minimize wound healing time following the procedure.

Once the incision has been formed, a spatula 24 such as, for example, a Castroviejo cyclodialysis spatula #E 0292 available from Stroz, Inc. having dimensions identical to that of the helical spatula, for example about 1 mm or less in width and 200 micrometers in thickness and having an end which is slightly modified by being polished to a point, is inserted through the incision to separate the lamella in the plane of the base of the incision (FIG. 6). The particular width of the spatula used of course depends upon the length of the incision. Following the initial separation of lamella with the blunt spatula 24, a shoehorn-type device 26 is inserted through the incision and laterally between the lamella as shown in FIG. 7. The shoehorn-type device 26 can be made of transparent plastic or stainless steel and measures about 0.9 mm in width by 3 mm in length. Its thickness is about 0.02 mm. The shoehorn-type instrument is utilized for facilitating insertion of a corkscrew delaminator or helicoidal spatula 28, for example a custom made Archi-

medes-screw dissector, as shown in FIG. 8. The flat corkscrew delaminator is used to carve a circular canal between the two corneal lamellae in which a gel such as a silicone gel is subsequently injected. The illustrated corkscrew delaminator consists of a flat wire about 1 mm or less in width, again depending upon incision length and 0.1 mm in thickness, and is curved to about 380°, that is superimposed by 20°. The spatula's edges are blunt or rounded as is its end.

As shown in FIG. 9, with the corkscrew delaminator, an annular track is made through the cornea at the preselected plane. A full 360° twisting motion of the helicoidal spatula 28 delaminates the cornea completely at the radial location of the incision, circumferentially of the central corneal zone. However, the central corneal zone is not delaminated as the helicoidal spatula 28 limits the delamination to an annular path at the radial locus of the incision. As shown in FIG. 10, the annular delamination results in the formation of an annular chamber or canal 30 opening on either side of the initial incision 20. Following the annular delamination, the helicoidal spatula 28 is removed by rotating the same with a reverse 360° twisting motion. When spatula 28 is removed, it may be necessary to ensure that the canal 30 openings on either side of the initial incision 20 are uniform to allow for the proper flow of gel through canal 30. A track width equalizer 31 (FIG. 17) is used for this purpose. Equalizer 31 contains a handle portion 31a, a curved portion 31b, and a rounded end portion 31c. End portion 31c, which typically measures 0.5 mm in diameter, is inserted through incision 20 into each canal 30 opening, thus insuring that the injected gel will pass through canal 30. Equalizer 31 is also used to remove the gel if necessary.

A corkscrew-like, preferably 30 gauge, needle 32, is then inserted by a 360° rotation into the annular channel 30. A syringe, for example, of 1 cc volume (not shown) filled with a biocompatible gel, is attached to the corkscrew needle 32 following insertion or prior to insertion into the annular channel 30. Examples of suitable biopolymeric materials for the gel are known biocompatible hydrogels (e.g. acrylic hydrogels, polyethylene oxides), silicone-based cross-linked elastomers, and other biopolymers (e.g. cross-linked hyaluronic acid). Specifically, one suitable gel is a transparent cross-linked methylvinylsiloxane gel with a modulus of elasticity of about 2000 N/m² and a refractive index of 1.402. Once the corkscrew needle is fully inserted, injection is started (FIG. 11). As the injection continues, the needle 32 is retracted so that gel 34 gradually fills the annular chamber as shown in FIG. 12. This process is continued until the track is fully filled with gel and the corkscrew needle has been removed therefrom.

It is also possible to inject gel 34 directly into canal 30 by using an automatic injector 40 (FIG. 16). Injector 40 consists of a powered injector unit 40a and

a gel cartridge unit 40b. Unit 40a can be controlled by a manual switch on the unit, or by a foot pedal switch. Cartridge 40b is a disposable sealed unit to prevent contamination, and fits onto unit 40a for easy, sterile operation. Injector 40 provides a consistent force to inject gel 34 into canal 30.

A small amount of gel escapes from the corneal incision due to over pressurisation (FIG. 11). Furthermore, subsequent to needle removal, an external massage is performed in order to evenly distribute the gel inside the canal. The remaining gel that appears at the incision is grabbed with forceps and cut, for example with scissors. Once the 30 gauge needle has been removed, gel fills the track creating a bulging of the corneal posterior lamellae and a flattening of the central corneal optical zone. FIG. 13a is a corneal cross-section illustrating the displacement of the corneal lamella when the needle 32 is disposed with an annular track 30. Once the needle has been retracted and gel fills the annular canal 30, a bulging of the corneal posterior lamella and a flattening of the central corneal optical zone occurs (FIG. 13b). Up to 13 diopters of flattening have been obtained with the technique of the invention. By removing a portion of the gel from the channel, the amount of corneal flattening can be reduced until emmetropization has been achieved. Intraoperative keratometry is suggested for determination of optimal corneal radius of curvature although other techniques could be employed.

Referring to FIG. 14, astigmatism is thought to be produced by localised corneal shear variations generated at the limbus. With the process of the invention, a reduction of existing astigmatism was observed experimentally. This phenomenon can be explained by a localized variation in gel distribution along the annular channel as shown. Indeed, because the pressure of the gel is constant, it equilibrates the radial stresses along the corneal meridian.

Astigmatism may also be corrected in accordance with the present invention by using a modified procedure as illustrated schematically in FIG. 15. In accordance with this modified procedure, a pair of arcuate channels 50 of approximately 90° in arc length and centered about the corneal center 52 are made by a stromal delaminator (not shown) which is a shorter version of the helicoidal delaminator discussed in detail above. A gel, as discussed above, is then injected into each of the arcuate channels 50 under keratometric control. The magnitude of the astigmatic optical correction in diopters is a function of the amount of gel injected into each of the arcuate channels 50, the size, that is diameter, width and angle of the arcuate channels, and the position of the two arcuate channels with respect to the patient's corneal astigmatic (flattest) axis 54.

As noted above, minimizing the length of the incision, in accordance with the invention, reduces

wound healing time. To further reduce wound healing time, following gel injection and the removal of any excess gel, the corneal incision can be instantly closed shut by applying a very small amount of collagen gel to the upper lips of the wound and cross linking it with ultraviolet radiation. Such sealing of the incision eliminates post operative patching of the eye and thus allows the patient to walk away from surgery without impediment. Ultraviolet cross linkable collagen gels are fabricated by several manufacturers and a suitable ultraviolet cross linkable collagen gel among those available could be readily ascertained.

Another advantage of the present invention over current surgical techniques is reversibility. Should it become necessary to readjust the curvature of the cornea at some later time, such as a year later, a linear incision is made above the channel to a depth which intersects the channel. The gel can then be removed by massaging the cornea as previously described until the desired corneal shape is obtained and then the incision is closed using the above described technique.

FIGS. 18a - 18e show alternative embodiments of a helicoidal delaminator or spatula for use in the present invention. Spatula 44 consists of a helicoidal section 44a, a planar support section 44b, and a handle section 44c which is fixed to support section 44b by welding or a similar attachment means. Handle 44c allows helicoidal spatula 44 to be more easily manipulated during surgery. The design of handle 44c, consisting of an annular cylindrical ring, is important, as it allows the surgeon an unobstructed view of the corneal surface as he is using the device.

FIG. 18b shows the cross-section of the helicoidal section 44a of spatula 44. It can be seen that section 44a imitates the radius of curvature of the cornea, which is approximately 7.8 millimeters, such that channel 30 closely parallels the surface curvature of the cornea.

In the embodiment shown in FIG. 18c, spatula 44 contains a nose portion 44d which is tapered along the top edge toward its end. When spatula 44 is used in the corneal surgical procedure described in the present invention, nose portion 44d creates a lamellar flap within the track formed by spatula 44 within the cornea. As can be seen in FIG. 19, lamellar flap 22a within cornea 22 aids in sealing channel 30 from incision 20, thus preventing gel from freely escaping from incision 20. Thus, this modification to spatula 44 eliminates the need for adhesives or the like to bond the incision in the cornea. Nose portion 44d tends to keep channel 30 in the lower portion of the cornea.

FIG. 18d shows an alternative embodiment of the end of spatula 44. Nose portion 44e is tapered along the bottom edge of section 44a toward its end. When spatula 44 is used in the corneal surgical procedure described in the present invention, nose portion 44e creates a channel as shown in FIG. 20. This channel

30 intersects incision 20 directly. Nose portion 44e tends to keep channel 30 in the upper portion of cornea 20.

FIG. 18e shows another alternative design for the end of spatula 44. Nose portion 44f is v-shaped at the end of spatula 44, and also creates a channel as shown in FIG. 20. Nose portion 44f tends to keep channel 30 in the middle portion of cornea 20.

While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiment, it is to be understood that the invention is not to be limited to the disclosed embodiment, but on the contrary is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.

Indeed, while the presently preferred incision location and depth have been specified have exemplary dimensions of instruments used in connection with the inventive procedure, it is to be appreciated that the gel viscosity, volume and disposition within the surgical annular track as well as the diameter of the track, width, depth and location are all parameters in the refractive change obtained in accordance with the invention.

Claims

1. A spatula for use in delaminarizing a portion of the cornea when altering the radius or curvature of the central cornea region, said spatula comprising a flat wire formed into a helicoidal shape and a handle means for manipulation of the said flat helicoidal wire to delaminarize said portion of the cornea.
2. A spatula as claimed in claim 1 comprising a flat wire formed in a helicoidal shape about an axis; a central portion connected to said wire at one end along the axis about which said wire is curved; and handle means connected to said central portion, by which said wire is rotated in order to delaminarize said cornea.
3. A spatula as claimed in claim 1 or claim 2 wherein the handle means has a structure giving the surgeon an unobstructed view of the corneal surface.
4. A spatula as claimed in claim 3 wherein said handle means comprises an annular member.
5. A spatula as claimed in any one of the preceding claims wherein said flat wire is curved to at least a 360 degree track.
6. A spatula as claimed in claim 5, wherein said flat wire is curved to encompass an approximately 380 degree track.
7. A spatula as claimed in any one of the preceding claims wherein the edges and end of said wire are rounded.
8. A spatula as claimed in any one of the preceding claims wherein the end is tapered along one edge.
9. A surgical kit for use in altering the radius of curvature of the central corneal region of the eye, comprising:
 - means for measuring the corneal thickness of the eye;
 - means for selecting an incision site at a predetermined distance from the central region of the cornea;
 - means, for insertion into the incision, for delaminarizing the cornea at the predetermined depth within the incision;
 - means, for insertion into the incision, for creating an annular channel in the cornea about the central region of the cornea;
 - a helicoidal spatula, for insertion into the incision, for creating an annular channel in the cornea about the central region of the cornea;
 - a guide device, for insertion into the incision, for facilitating the insertion of the helicoidal spatula into the cornea;
 - a channel equalizing device, for insertion into the incision, for ensuring the proper size of the channel entry on the incision;
 - and injector means, for insertion into the incision, for introducing a biocompatible gel into the channel to alter the radius of curvature of the cornea.

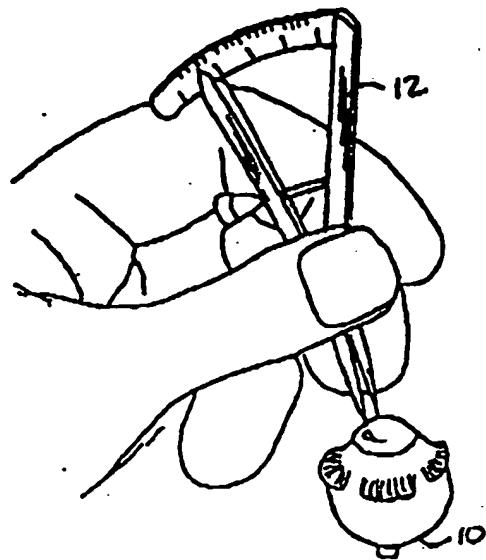


Fig. 1

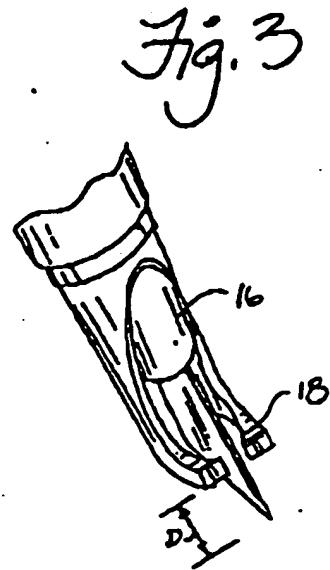


Fig. 3

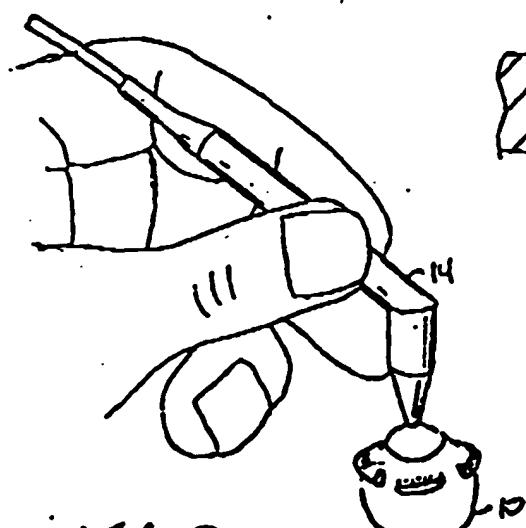


Fig. 2

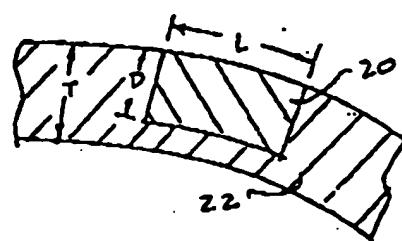


Fig. 4

Fig. 7

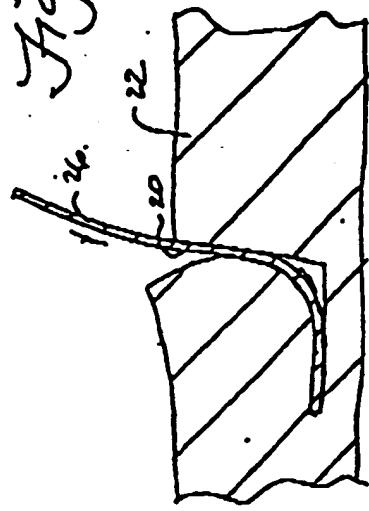


Fig. 8

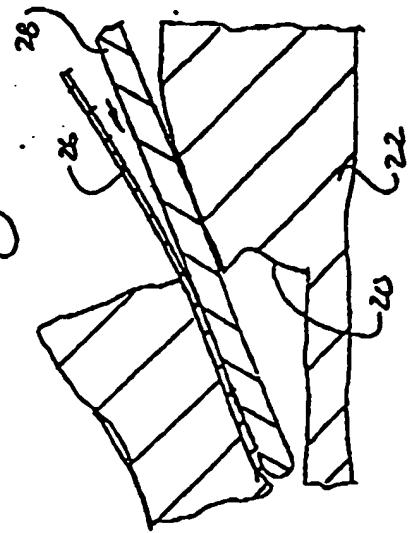


Fig. 5

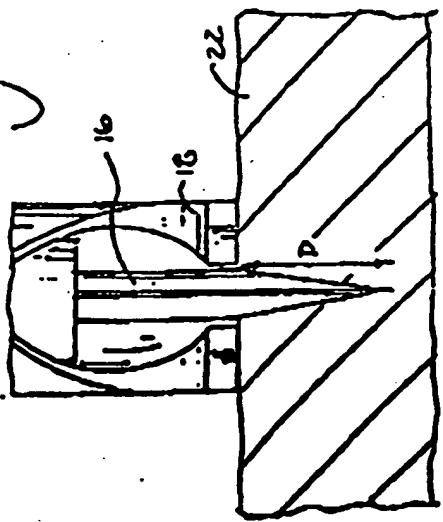
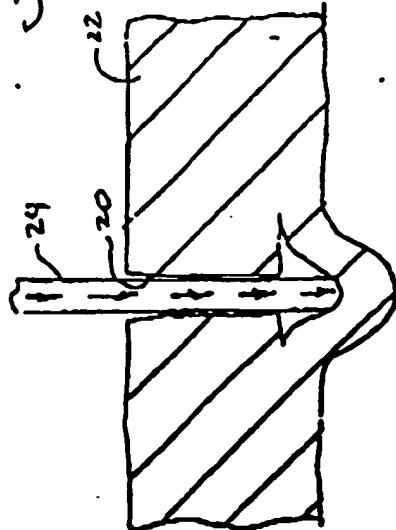


Fig. 6



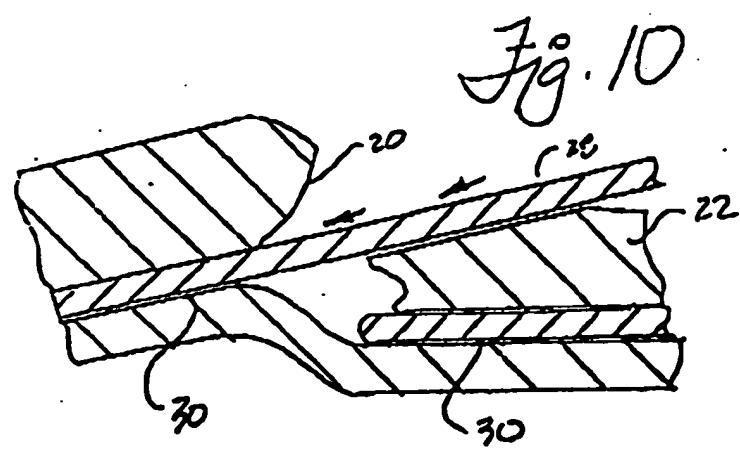
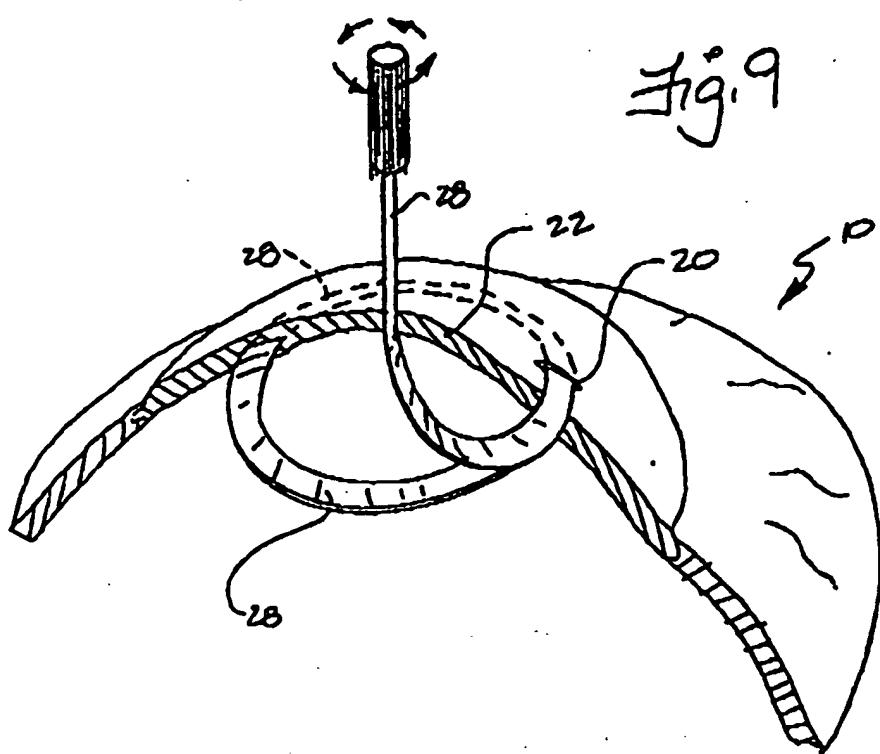


Fig. 11

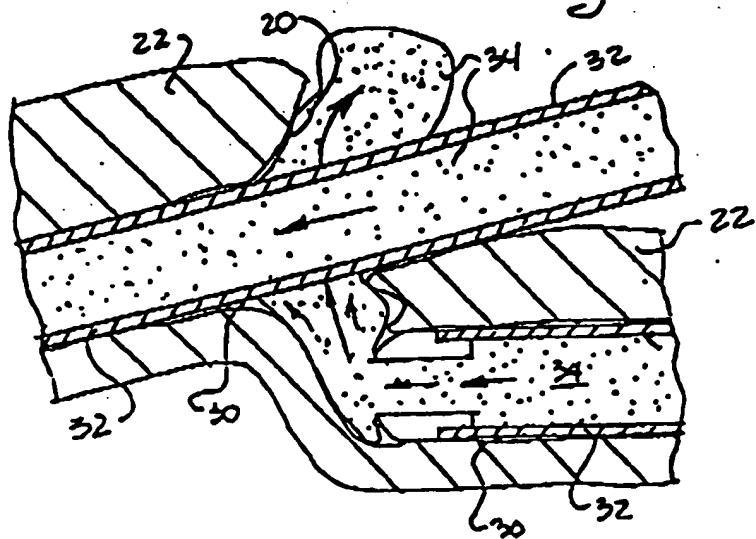
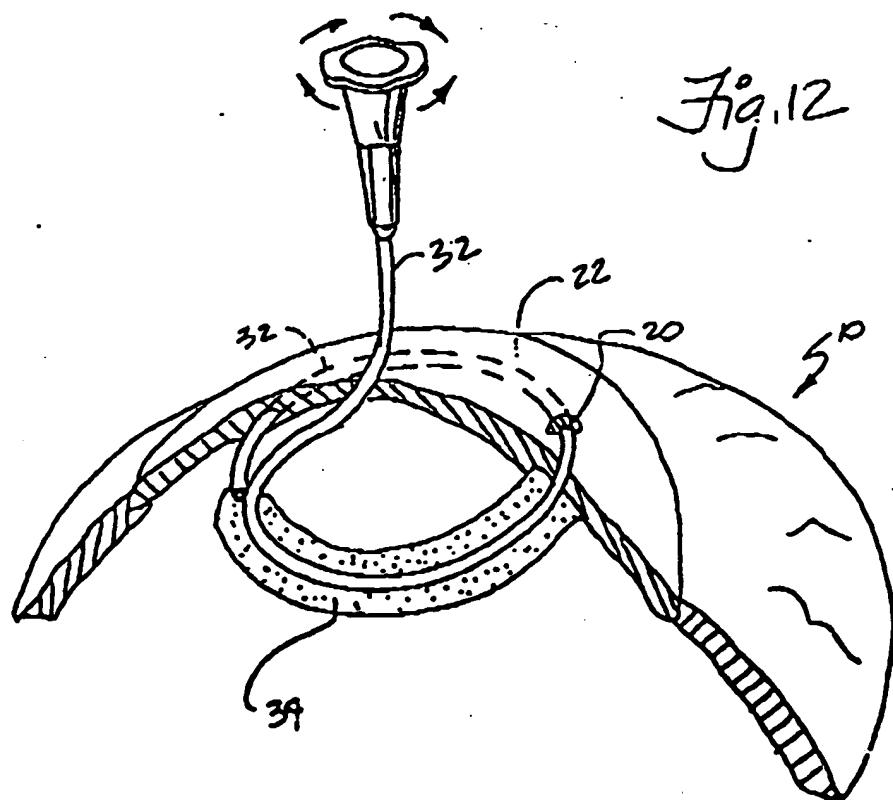


Fig. 12



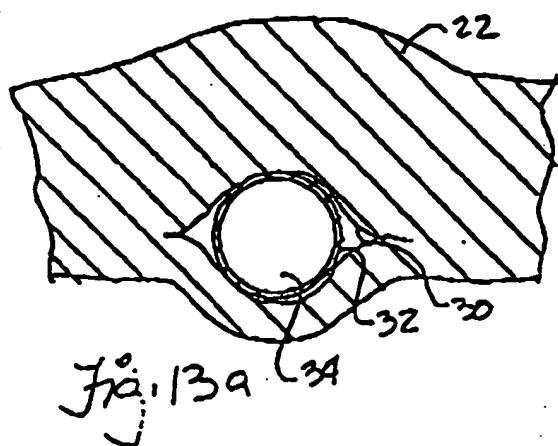


Fig. 15

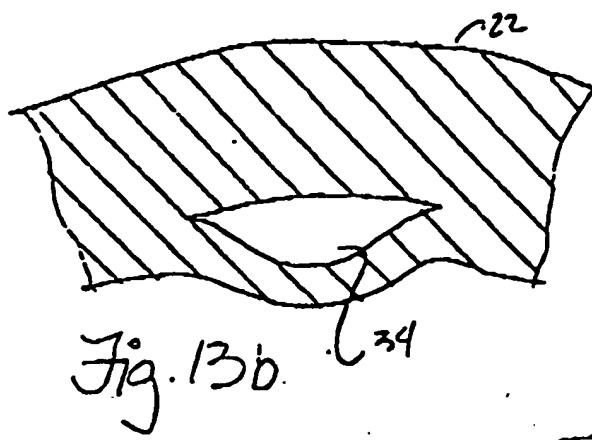
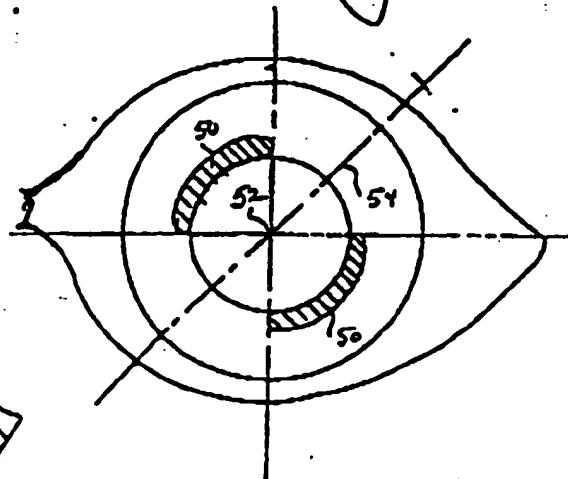
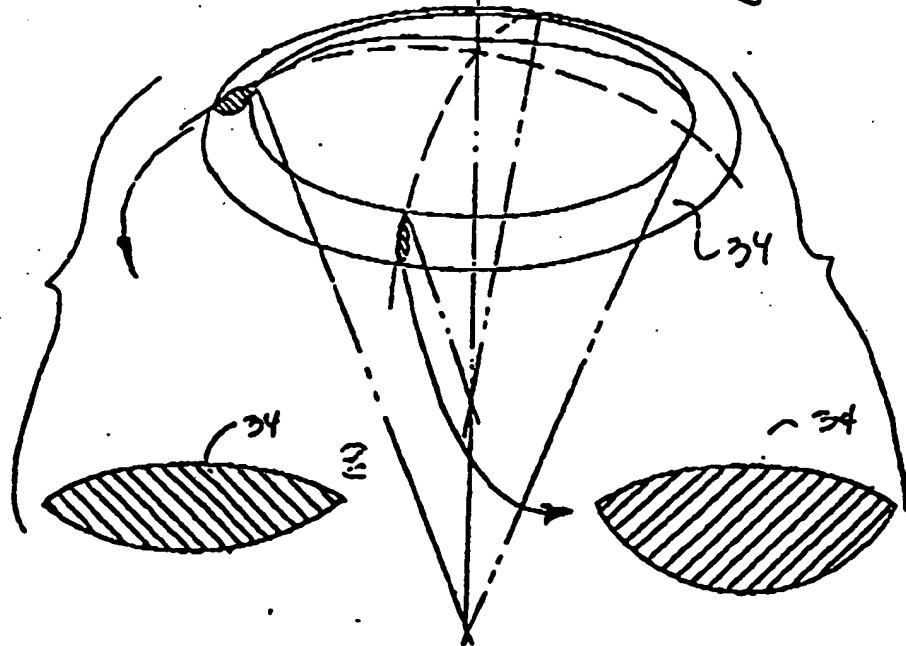
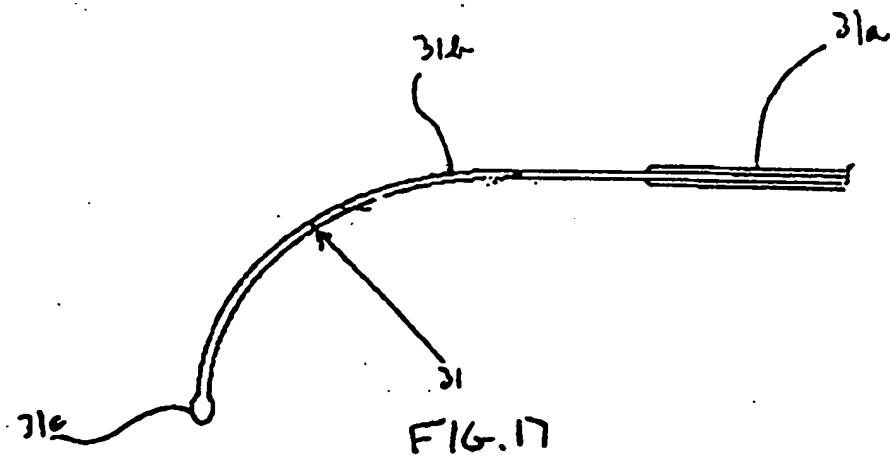
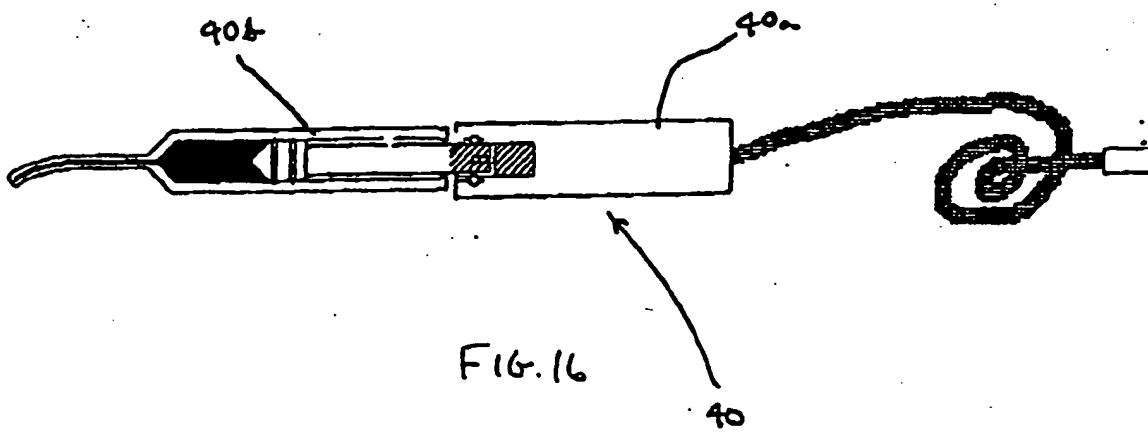
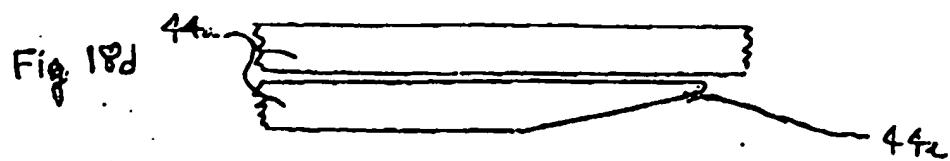
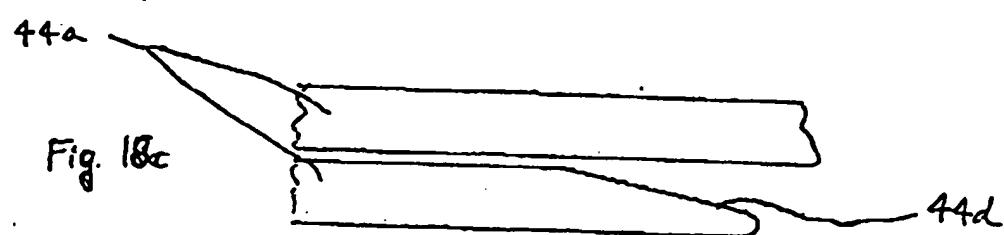
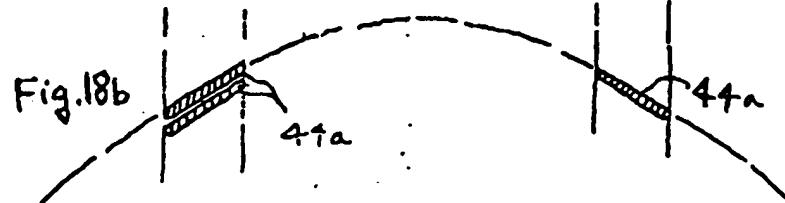
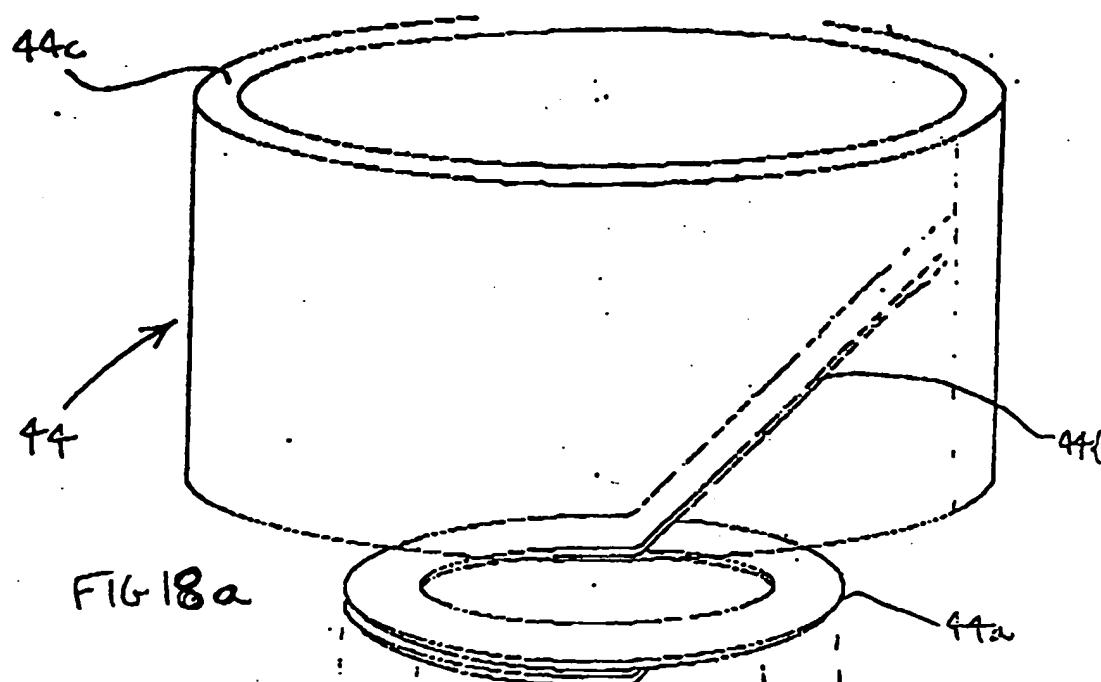
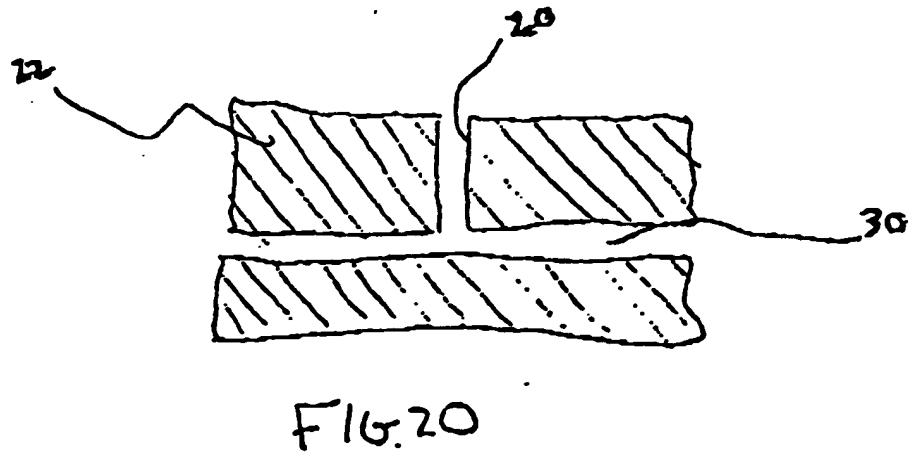
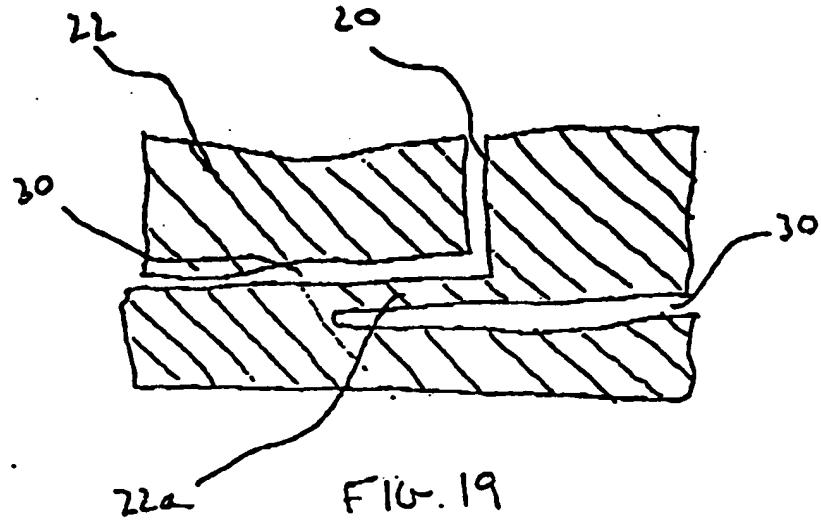


Fig. 14











European Patent
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EUROPEAN SEARCH REPORT

Application Number

EP 93 30 1245

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. CL.5)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X	WO-A-8 810 096 (KERAVISION) * page 12, line 7 - line 21; figures 5-8,11-14 *	1-6,8 9	A61F9/00 A61F2/14
X	EP-A-0 083 494 (A.E. REYNOLDS) * page 14, line 25 - page 15, line 18; figures 5,8,10 *	1,2,5-8	
A	DE-A-2 811 869 (V. GEUDER) * claim 1; figures 1,5,7 *	3,4	
A	US-A-4 598 714 (F.B. KREMER ET AL.) * abstract *	9	
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The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	13 APRIL 1993	WOLF C.	
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, not published on, or after the filing date D : document cited in the application L : document cited for other reasons A : member of the same patent family, corresponding document	
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